

participants in the United States will address the implications of the findings and conclusions of this report in the context of domestic research.

3. In the United States, committees that review the ethics of human research protocols are referred to in regulation and practice as Institutional Review Boards (IRBs). In other countries, different names might be used, such as research ethics committees or ethics review committees. In this report, references and recommendations that are specific to the United States will refer to these committees as IRBs. References and recommendations that refer to such committees generally regardless of their geographic location will call them ethics review committees.

4. Although these protections are generally meant to apply to all research involving more than minimal risk, there are exceptions in certain guidelines for informed consent to be waived in research involving minimal risk.

FOR FURTHER INFORMATION ABOUT THE REPORT CONTACT: Eric M. Meslin, Ph.D., Executive Director, National Bioethics Advisory Commission, or to obtain copies of the report contact the NBAC office at 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, telephone number (301) 402-4242, fax number (301) 480-6900. Copies may also be obtained through the NBAC website: www.bioethics.gov.

Dated: May 9, 2001.

Eric M. Meslin,

Executive Director, National Bioethics Advisory Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E-1413]

Determination of Regulatory Review Period for Purposes of Patent Extension; Xenical

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Xenical and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Xenical (orlistat). Xenical is a lipase inhibitor indicated for obesity management that acts by inhibiting the absorption of dietary fats. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Xenical (U.S. Patent No. 4,598,089) from HLR Technology Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 7, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Xenical

represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Xenical is 3,969 days. Of this time, 3,091 days occurred during the testing phase of the regulatory review period, while 878 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 12, 1988. The applicant claims June 24, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 12, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* November 27, 1996. The applicant claims November 26, 1996, as the date the new drug application (NDA) for Xenical (NDA 20-766) was initially submitted. However, FDA records indicate that NDA 20-766 was submitted on November 27, 1996.

3. *The date the application was approved:* April 23, 1999. FDA has verified the applicant's claim that NDA 20-766 was approved on April 23, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,824 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by July 16, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 15, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information

are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01-12093 Filed 5-14-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0192]

Draft Guidance for Industry on Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution." The draft guidance is intended to assist establishments that are required to register ("registrants") and submit listing information for drugs and biological products in obtaining and submitting the necessary forms to meet registration and listing requirements; this draft guidance will also assist those private label distributors that are not required to register, but elect to submit designated information directly to FDA. FDA proposes to make available through the Internet, rather than through conventional mail, the following registration and listing forms: Form FDA 2656 (Registration of Drug Establishment), Form FDA 2656e (Annual Update of Drug Establishment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors).

DATES: Submit written comments on this draft guidance document by July 16, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD-

240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For human drugs: Kathy Smith, Center for Drug Evaluation and Research (HFD-90), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-1086.

For biological drugs: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373, yetter@cber.fda.gov.

For veterinary drugs: Lowell Fried, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0165, lfried@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under part 207 (21 CFR part 207), as authorized and required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 amd 264), establishments (e.g. manufacturers, repackers, and relabelers) engaged in the manufacture, preparation, propagation, compounding, or processing of human drugs, veterinary drugs, and biological products, with certain exceptions, are required to register and submit listing information.

Under part 207, these "registrants" use Form FDA 2656 to submit establishment registration information and to submit annual re-registration information (FDA had also used Form FDA 2656e for annual re-registration, but this form will no longer be necessary); private label distributors use Form FDA 2656 to obtain a labeler code; registrants and, in some cases, private label distributors use Form FDA 2657 to submit listing information for drugs and biological products and to update listing information; and registrants use Form FDA 2658 to submit listing information for private label distributors (FDA has also used the compliance verification

report for updating listing information). Registrants will use new Form FDA 3356 to submit establishment and listing information for those human cells, tissues, and cellular and tissue-based products regulated as drugs and/or biological products under the act and section 351 of the PHS Act beginning January 21, 2003.

If a registrant or private label distributor prefers to receive any of these forms through conventional mail, they may direct such requests to the designated agency contacts. Under the draft guidance, information previously submitted on Form FDA 2656e would be submitted on Form FDA 2656. Distribution of these forms through the Internet will reduce administrative costs to the agency. The draft guidance also contains registration information applicable to human cells, tissue, and cellular and tissue-based product establishments.

The draft guidance explains that, unless specifically requested otherwise, FDA is discontinuing the conventional mailing of these forms to registrants and private label distributors. These forms are available on the Internet. Registrants, and if appropriate, private label distributors must continue to submit completed forms to FDA in accordance with the registration and listing requirements in part 207. The draft guidance explains where to obtain the forms on the Internet, how to make changes to information, and where to submit completed forms.

Internet availability of these forms (instead of availability by conventional mail) is part of an agency initiative to use modern technology to facilitate the submission of establishment registration and listing information. FDA is developing software to make possible the electronic submission of the requisite registration and listing information for drugs and biological products. The agency plans to propose rulemaking that would revise the requirements for registration and listing and would require registrants to submit this information electronically.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.